

(b) The PACE organization must develop a program to ensure that all staff furnishing direct participant care services meet the following requirements:

(1) Comply with any State or Federal requirements for direct patient care staff in their respective settings.

(2) Comply with the requirements of § 460.68(a) regarding persons with criminal convictions.

(3) Have verified current certifications or licenses for their respective positions.

(4) Are free of communicable diseases.

(5) Have been oriented to the PACE program.

(6) Agree to abide by the philosophy, practices, and protocols of the PACE organization.

[67 FR 61505, Oct. 1, 2002]

EFFECTIVE DATE NOTE: At 67 FR 61505, Oct. 1, 2002, § 460.71 was added, effective Oct. 31, 2002.

§ 460.72 Physical environment.

(a) *Space and equipment*—(1) *Safe design.* A PACE center must meet the following requirements:

(i) Be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors.

(ii) Ensure a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services that protects the dignity and privacy of the participant.

(2) *Primary care clinic.* The PACE center must include sufficient suitable space and equipment to provide primary medical care and suitable space for team meetings, treatment, therapeutic recreation, restorative therapies, socialization, personal care, and dining.

(3) *Equipment maintenance.* A PACE organization must establish, implement, and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations.

(b) *Fire Safety.* (1) Except as provided in paragraph (b)(2) of this section, a PACE center must meet the occupancy provisions of the 1997 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference) that apply to the

type of setting in which the center is located. Incorporation by reference of the Life Safety Code, 1997 edition, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The Life Safety Code is available for inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., Washington, D.C. Copies of the Life Safety Code may be obtained from the National Fire Protection Code (NFPA), 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101. If any changes in the Life Safety Code, 1997 edition, are also to be incorporated by reference, notice to that effect will be published in the FEDERAL REGISTER.

(2) *Exceptions.* (i) The Life Safety Code provisions do not apply in a State in which CMS determines that a fire and safety code imposed by State law adequately protects participants and staff.

(ii) CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the center, but only if the waiver does not adversely affect the health and safety of the participants and staff.

(c) *Emergency and disaster preparedness*—(1) *Procedures.* The PACE organization must establish, implement, and maintain documented procedures to manage medical and nonmedical emergencies and disasters that are likely to threaten the health or safety of the participants, staff, or the public.

(2) *Emergencies defined.* Emergencies include, but are not limited, to the following:

(i) Fire.

(ii) Equipment, water, or power failure.

(iii) Care-related emergencies.

(iv) Natural disasters likely to occur in the organization's geographic area. (An organization is not required to develop emergency plans for natural disasters that typically do not affect its geographic location.)

(3) *Emergency training.* A PACE organization must provide appropriate training and periodic orientation to all staff (employees and contractors) and participants to ensure that staff demonstrate a knowledge of emergency

procedures, including informing participants what to do, where to go, and whom to contact in case of an emergency.

(4) *Availability of emergency equipment.* Emergency equipment, including easily portable oxygen, airways, suction, and emergency drugs, along with staff who know how to use the equipment, must be on the premises of every center at all times and be immediately available. The organization must have a documented plan to obtain emergency medical assistance from sources outside the center when needed.

(5) *Annual test of emergency and disaster plan.* At least annually, a PACE organization must actually test, evaluate, and document the effectiveness of its emergency and disaster plans.

§ 460.74 Infection control.

(a) *Standard procedures.* The PACE organization must follow accepted policies and standard procedures with respect to infection control, including at least the standard precautions developed by the Centers for Disease Control and Prevention.

(b) *Infection control plan.* The PACE organization must establish, implement, and maintain a documented infection control plan that meets the following requirements:

(1) Ensures a safe and sanitary environment.

(2) Prevents and controls the transmission of disease and infection.

(c) *Contents of infection control plan.* The infection control plan must include, but is not limited to, the following:

(1) Procedures to identify, investigate, control, and prevent infections in every center and in each participant's place of residence.

(2) Procedures to record any incidents of infection.

(3) Procedures to analyze the incidents of infection to identify trends and develop corrective actions related to the reduction of future incidents.

§ 460.76 Transportation services.

(a) *Safety, accessibility, and equipment.* A PACE organization's transportation services must be safe, accessible, and equipped to meet the needs of the participant population.

(b) *Maintenance of vehicles.* (1) If the PACE organization owns, rents, or leases transportation vehicles, it must maintain these vehicles in accordance with the manufacturer's recommendations.

(2) If a contractor provides transportation services, the PACE organization must ensure that the vehicles are maintained in accordance with the manufacturer's recommendations.

(c) *Communication with PACE center.* The PACE organization must ensure that transportation vehicles are equipped to communicate with the PACE center.

(d) *Training.* The PACE organization must train all transportation personnel (employees and contractors) in the following:

(1) Managing the special needs of participants.

(2) Handling emergency situations.

(e) *Changes in care plan.* As part of the multidisciplinary team process, PACE organization staff (employees and contractors) must communicate relevant changes in a participant's care plan to transportation personnel.

§ 460.78 Dietary services.

(a) *Meal requirements.* (1) Except as specified in paragraphs (a)(2) or (a)(3) of this section, the PACE organization must provide each participant with a nourishing, palatable, well-balanced meal that meets the daily nutritional and special dietary needs of each participant. Each meal must meet the following requirements:

(i) Be prepared by methods that conserve nutritive value, flavor, and appearance.

(ii) Be prepared in a form designed to meet individual needs.

(iii) Be prepared and served at the proper temperature.

(2) The PACE organization must provide substitute foods or nutritional supplements that meet the daily nutritional and special dietary needs of any participant who has any of the following problems:

(i) Refuses the food served.

(ii) Cannot tolerate the food served.

(iii) Does not eat adequately.

(3) The PACE organization must provide nutrition support to meet the